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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/809,677	02/20/2002	Edward F. Myers	07354/004001	7900

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EXAMINER

KIM, SUN U

ART UNIT	PAPER NUMBER
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1723

DATE MAILED: 10/03/2002

24

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
08/809,677

Applicant(s)
Myers

Examiner
John Kim

Art Unit
1723



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Feb 20, 2002
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-43 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-27 and 30-43 is/are rejected.
- 7) ☒ Claim(s) 28 and 29 is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on Feb 20, 2002 is/are a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other: _____

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1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 1, 7, 16, 26 and 41 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claims 1, 16, 26 and 41, the phrase "such as" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

Recitation of "the biological fluid loop" in claim 7 lacks a positive antecedent basis.

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1-2, 7-8, 12, 14-17, 21, 24-27, 32, 35, 37-38 and 41-42 are rejected under 35 U.S.C. 102(b) as being anticipated by Olumide et al., "Hepatic support with hepatocyte suspensions in a permeable membrane dialyzer", Surgery, November 1977, Vol. 82, No. 5, pages 599-606 (hereinafter referred to as Olumide et al.). Olumide et al. teach method and apparatus for extracorporeal purification of blood and plasma comprising a membrane dialyzer having inlet and outlet ports for blood and inlet and outlet ports for hepatocytes and culture medium, a semi-permeable membrane separating a first conduit for blood circulation and a second conduit for

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hepatocytes and culture medium circulation, a mixing vessel connected to a second conduit and has an inlet port for introducing hepatocytes, an oxygenation means in fluid communication with the mixing vessel, a pump for circulating blood through the first conduit and a pump for circulating hepatocytes and culture medium from the mixing vessel to the second conduit (see figure 3; pages 600-602)(claims 1-2, 16, 26-27, 41). Regarding claim 7, the structural elements comprising blood circuit of Olumide et al. are inherently made of material compatible with blood. Regarding claims 8 and 32, Olumide et al. teach that hepatocytes are isolated from liver tissue of pigs (see page 599). Regarding claims 12, 14-15, 24-25, 35 and 37-38, Olumide et al. teach that curophan membrane of the membrane dialyzer are impermeable to high molecular weight proteins and partially permeable to low molecular weight proteins (see pages 605-606). Regarding claim 17, Olumide et al. teach that blood is circulated through the dialyzer at a flow rate of 150 - 250 ml/min (see page 601). Regarding claim 21, Olumide et al. teach that blood and culture medium is maintained at 37 degree Celsius via a heat exchanger (see figures 1-2; page 600). Regarding claim 42, the hepatocytes of Olumide et al. are unattached (see page 599).

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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6. Claims 18-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Olumide et al. Olumide et al. teach a method of using the apparatus for extracorporeal purification of blood and plasma as described in above paragraph 4. It would have been obvious to a person of ordinary skills in the art to adjust the flow rate of culture medium containing hepatocytes, circulation period, replenishment of hepatocytes and culture medium during circulation period to achieve optimal purification of blood.

7. Claims 3-6, 9, 11, 22-23, 30-31, 33 and 43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Olumide et al. as applied to claims 1, 16, 26, 41 above, and further in view of U.S. Patent No. 5,043,260 (hereinafter referred to as Jauregui). Claims 3-4, 22-23 and 30-31 differ from the apparatus and the method of Olumide et al. in reciting additional means for removal of solutes connected to the bioreactor and the mixing vessel. Jauregui teaches a method of using the apparatus for extracorporeal purification of blood and plasma comprising hollow fiber perfusion device with hepatocytes including the means for removal of solutes from hepatocytes in culture medium (62) and blood connected to the hollow fiber perfusion device (10) (see figures 1, 4, 7; col. 4, line 39 - col. 5, line 15). It would have been obvious to a person of ordinary skills in the art to modify the apparatus and the method of Olumide et al. to incorporate additional means for removal of solutes connected to the bioreactor to remove waste products in culture medium and blood released by hepatocytes as suggested by Jauregui. Regarding claim 5, Jauregui teaches ultrafiltration membrane (see col. 4, lines 49-56). Regarding claim 6, it would have been obvious to a person of ordinary skills in the art to substitute hollow fiber membrane dialyzer for the

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membrane dialyzer of Olumide et al. for their equivalent function as dialyzers and have the lumen within the fiber as the first conduit and the exterior space of the fiber as the second conduit as suggested by Jauregui. Regarding claim 11, it would have been obvious to a person of ordinary skills in the art to modify the apparatus of Olumide et al. to use any pump to circulate biological fluid through a hollow fiber membrane such as a centripetally forced pump. Regarding claims 9 and 33, it would have been obvious to a person of ordinary skills in the art to substitute hepatocytes isolated from the liver cells of human in the apparatus of Olumide et al. for hepatocytes isolated from the liver cells of pig for purification of human blood. Regarding claim 43, it would have been obvious to a person of ordinary skills in the art to use the hepatocytes attached to the membrane dialyzer for purifying blood as suggested by Jauregui (see col. 4, lines 4-34).

8. Claims 10 and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Olumide et al. as applied to claims 1 and 27 above, and further in view of U.S. Patent No. 4,335,994 (hereinafter referred to as Gurth). It would have been obvious to a person of ordinary skills in the art to modify the apparatus of Olumide et al. to use any pump to circulate biological fluid through a loop such as a boundary layer pump of Gurth.

9. Claims 13 and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Olumide et al. as applied to claims 1 and 27 above, and further in view of U.S. Patent No. 5,011,607 (hereinafter referred to as Shinzato). It would have been obvious to a person of ordinary skill in

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the art to modify the apparatus of Olumide et al. to use any pump to generate a counterflow for back diffusion such as a volume changing pump device (8) of Shinzato (see abstract and figure 1).

10. Claims 39-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Olumide et al. as applied to claim 26 above, and further in view of Arnaout et al., "Development of Bioartificial Liver: Bilirubin Conjugation in Gunn Rats", Journal of Surgical Research, April 1990, Vol. 48, No. 4, pages 379-382 (hereinafter referred to as Arnaout et al.). Claims 39-40 essentially differ from the apparatus of Olumide et al. in reciting hepatocytes attached to microcarrier particles comprising collagen-coated beads. Arnaout et al. teach an apparatus for extracorporeal purification of blood and plasma comprising isolated hepatocytes attached to collagen-coated microcarriers for expression of differentiated cell function and maintaining viability of hepatocytes. It would have been obvious to a person of ordinary skills in the art to modify the apparatus of Olumide et al. to substitute hepatocytes attached to collagen-coated microcarriers for prolonged viability and expressed differentiated liver cell function for more efficient removal of waste material from blood.

11. Claims 28-29 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

12. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. References cited on PTO-892 teach bioartificial livers.

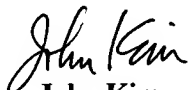
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13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to John Kim whose telephone number is (703) 308-2350. The examiner can normally be reached on weekdays from 7:00 AM - 3:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Wanda Walker, can be reached on (703) 308-0457. The fax phone number for official response after final action is (703) 872-9311, and the fax phone number for all other official faxes is (703) 872-9310.

When sending a draft amendment by fax, please mark the paper as "DRAFT"; otherwise, mark the paper "OFFICIAL". This will expedite the processing of the paper.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0651.


John Kim
Primary Examiner
Art Unit 1723

J. Kim
September 28, 2002